REMARKS

Reconsideration of this application is respectfully requested. Claims 47-56 and 89 are pending and at issue.

Enablement Rejection

Claims 47-56 and 89 have been rejected for lack of enablement. The Examiner maintains that the specification only enables a composition comprising benzethonium chloride and sodium dehydroacetate because synergism has not been shown for other benzethonium salts and other salts of dehydroacetic acid.

According to the Examiner, the specification only enables the disclosed species for the reason that "species within each genus differ in size, functionality, polarity as well as other chemical and physical properties all of which will affect a compound's activity. I[n] fact, certain chemical functionalities of the claimed genus may yield antagonistic activity." Office Action at page 2.

"[T]he examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention." MPEP § 2164.04 (citing *In re Wright*, 999 F.2d 1557, 1562 (Fed. Cir. 1993)).

Applicant respectfully submits that the Examiner has failed to establish a reasonable basis for questioning the enablement provided by the specification. The Examiner provides nothing more than unsupported speculation that combinations of different salts would have different activities, although the ions having biocidal activity remain the same. For instance, there is no reasonable basis to believe that other salts of benzethonium or dehydroacetate will yield "antagonistic" activity as asserted by the Examiner.

The Examiner argues that species within each genus differ in "size, functionality, polarity as well as other chemical and physical properties." The compounds in question (with the exception of dehydroacetic acid) are salts of specific active moieties (i.e., benzethonium and

dehydroacetate). The activity of these compounds is derived from their constituent active ions (i.e., the benzethonium cation and the dehydroacetate anion).

As has been previously pointed out, a source of the biocidal activity in the benzethonium is the benzethonium ion. *See, e.g.*, U.S. Patent No. 4,877,617. Similarly, because both sodium dehydroacetate and dehydroacetic acid possess biocidal activity (*see, e.g.*, Tables 1 and 3, respectively, of the specification), it is readily apparent that activity resides in the dehydroacetate component.

Nothing in the record suggests that varying the salt form of benzethonium or dehyroacetate will deprive them of their biocidal activity. In fact, a skilled artisan would readily recognize that in solution these salts will dissociate leaving the active benzethonium cation and dehydroacetate anion. Accordingly, any combination of salts from each genus will provide the ions for which biocidal activity is known and synergy has been found.

Furthermore, when a representative example of a claimed genus is enabled, "[p]roof of enablement will be required for other members of the claimed genus only where adequate reasons are advanced by the examiner to establish that a person skilled in the art could not use the genus as a whole without undue experimentation." MPEP § 2164.03. Applicant respectfully submits that the Examiner has failed to provide adequate reasons for why one of ordinary skill in the art, after reading the working examples disclosed in the specification, could not use the entire genus of benzethonium salts and dehyroacetates without undue experimentation.

The specification demonstrates that a combination of benzethonium chloride and sodium dehydroacetate produces a synergistic antibacterial effect. *See, e.g.*, Example 1 (Table 1) of the specification. Although the Office Action states that "no examples of synergism have been provided for dehydroacetic acid" (Office Action at page 3), the specification does, in fact, also demonstrate synergism for the combination of benzethonium chloride and dehydroacetic acid. *See* Example 2 (Table 3).

Factors to consider when determining whether the enablement requirement is satisfied (the "*Wands* factors") include (a) the breadth of the claims, (b) the nature of the invention, (c) the

state of the prior art, (d) the level of one of ordinary skill, (e) the level of predictability in the art, (f) the amount of direction provided by the inventor, (g) the existence of working examples, and (h) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. MPEP § 2164.01(a).

(A) The breadth of the claims

The claims recite benzethonium salts and dehyroacetic acid and its salts. Each genus include at least one active ion— benzethonium and dehydroacetate, respectively. As noted above, these ions represent active biocidal moieties. In this respect, the claims are narrow because they relate to two particular active moieties.

(B) The nature of the invention and (C) The state of the prior art

The invention relates to a preservative formulation comprising a synergistic combination of well-defined salts and acids. Those skilled in the art are familiar with these components and antibacterial formulations comprising them. *See, e.g.*, U.S. Patent No. 4,877,617.

(D) The level of one of ordinary skill and (E) The level of predictability in the art

The level of skill in the art is relatively high. The skilled artisan can readily prepare formulations of the claimed components and determine whether the formulations are synergistic.

(F) The amount of direction provided by the inventor

The inventor provides significant guidance in the specification. Specific benzethonium and dehydroacetate salts and amounts for them are provided in the specification. *See*, for example, page 4, lines 14-16; page 6, lines 17-19; page 9, lines 10-13. The specification also discloses particular compositions demonstrating the claimed synergism and provides detailed instructions for preparing and testing the compositions. *See* Examples 1, 2, and 4-7.

(G) The existence of working examples

The specification provides working examples for species in each claimed genus. Moreover, the examples are representative of the entire scope of the claimed invention because they include the two active moieties specifically claimed (benzethonium and dehydroacetate).

(H) The quantity of experimentation needed to make or use the invention

As noted, the specification provides detailed instructions for making and using the compositions of the claimed invention. Because one skilled in the art is well-versed in the chemistry of salts, little experimentation would be necessary to develop formulations containing other salt forms of benzethonium and dehyroacetate to practice the entire scope of the claims. Furthermore, the preparation and testing of the formulations is routine in the art. *See* MPEP §2164.06 ("'The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed.'" *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (citing *In re Angstadt*, 537 F.2d 489, 502-04, 190 USPQ 214, 217-19 (CCPA 1976))").

For the foregoing reasons, the claims are enabled and Applicant respectfully requests withdrawal of this rejection.

Request for Interview

In view of the above remarks, Applicant believes the pending application is in condition for allowance. If the Examiner remains unconvinced, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below to schedule an interview.

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Respectfully submitted,

By /Jay P. Lessler/
Jay P. Lessler
Registration No.: 41,151
DARBY & DARBY P.C.
P.O. Box 770
Church Street Station
New York, New York 10008-0770
(212) 527-7700
(212) 527-7701 (Fax)
Attorneys/Agents For Applicant